

Application Number 10/723,316  
Amendment responsive to Office Action mailed May 9, 2007

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REMARKS

This Amendment is responsive to the Office Action dated May 9, 2007. Applicant has amended claims 1, 7, 9, 23, 28, 29, 30 and 39. Claims 1, 3-5, 7-11, 14, 20-30 and 33-39 are pending.

Allowable Subject Matter

The Office Action indicated that claims 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Office Action also indicated that claims 36-38 are allowed. Applicant appreciates these indications of allowability with respect to claims 33-38.

Interpretation of "Adjacent" is unreasonable

Applicant maintains that the Office's interpretation of the term "adjacent" in a number of Applicant's claims is unreasonable, and therefore reversible error, for at least the reasons stated in Applicant's previous submission. Nevertheless, in order to advance prosecution, Applicant has amended independent claims 1, 28, 30 and 39 to specify that stimulation pulses are delivered to the specific target pelvic locations recited in the claims. None of the applied references disclose or suggest delivering stimulation to the particular locations recited in the independent claims in a configuration effective to provide at least partial relief from the particular pelvic floor disorders specified in the independent claims.

Claim Rejection Under 35 U.S.C. § 102

US 2005/0209652 to Whitehurst et al. (Whitehurst)

The Office Action rejected claims 1, 3, 4, 5, 7-9, 11, 14, 20, 23 and 25-27 under 35 U.S.C. § 102(e) as being anticipated by Whitehurst. Applicant respectfully traverses this rejection to the extent such rejection is considered applicable to the claims as amended. Whitehurst fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

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For example, Whitehurst fails to disclose or suggest a method of treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia comprising delivering electrical stimulation pulses to one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Instead, as recognized in the Office Action, Whitehurst describes stimulating structures of the penis including the corpus cavernosa, corpus spongiosum, prostatic plexus, urethra, or pelvic splanchnic nerves. Whitehurst's disclosure of delivering stimulation to the penis would not have suggested delivering stimulation pulses to any of the specific locations recited by amended independent claim 1 to one of ordinary skill in the art. For at least these reasons, Whitehurst fails to disclose or suggest the requirements of Applicant's independent claim 1.

Additionally, Whitehurst fails to disclose or suggest that the stimulation lead comprises a beam steering lead comprising multiple electrodes, as required by claim 3. Paragraph [0121] of the present application refers to examples of beam steering leads. Nothing within Whitehurst remotely suggests use of such leads with the stimulators and for the applications described therein.

Whitehurst also fails to disclose or suggest a lead comprising at least one electrode selected from the group consisting of an electrode formed from a portion of wire, a barb or a hook, a spherically-shaped electrode, and a helically-shaped electrode, as required by claim 11.

For at least these reasons, the Office Action has failed to establish a *prima facie* case for anticipation of Applicant's claims 1, 3, 4, 5, 7-9, 11, 14, 20, 23 and 25-27 by Whitehurst under 35 U.S.C. § 102(e). Withdrawal of this rejection is respectfully requested.

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*US 5,454,840 to Krakovsky et al. (Krakovsky)*

The Office Action also rejected claims 1, 7-8, 14 and 20-29 under 35 U.S.C. § 102(b) as being anticipated by Krakovsky. Applicant respectfully traverses this rejection to the extent such rejection is considered applicable to the claims as amended. Krakovsky fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Krakovsky fails to disclose or suggest a method of treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia comprising delivering electrical stimulation pulses to one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thercof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Instead, as recognized in the Office Action, Krakovsky describes stimulation of the pelvic splanchnic nerve or pudendal nerve for treatment of sexual dysfunction and stimulation of the urethra to correct female urinary incontinence during sexual intercourse. The disclosure of pelvic splanchnic nerve, pudendal nerve, and urethra stimulation in Krakovsky would not have suggested stimulation delivery to any of the different locations recited by amended independent claim 1 to one of ordinary skill in the art.

In support of the rejection of claim 1 as previously presented, the Office Action reasoned that implantation of a medical lead adjacent to the pelvic splanchnic nerves and/or the pudendal nerves necessarily results in a lead implanted adjacent to other nerves, because “adjacent” can be interpreted to mean close but not necessarily touching. However, Applicant’s claim 1 is currently amended to clarify that the stimulation pulses are in fact delivered to one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof. Krakovsky’s disclosure of delivering stimulation to the pelvic splanchnic nerves and/or

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the pudendal nerves is in no way a disclosure of delivering stimulation to any of the specific locations cited in claim 1.

With respect to amended independent claim 28, Krakovsky fails to disclose or suggest a method for treating urinary retention disorder comprising delivering electrical stimulation pulses to one of the pudendal nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof.

Krakovsky does not even teach or suggest treating urinary retention disorder, as required by claim 28, and instead describes treating sexual dysfunction and female urinary incontinence during sexual intercourse. Additionally, Krakovsky lacks any disclosure that suggests stimulation delivery to any of the locations recited by amended independent claim 28 for any reason, much less treatment of urinary retention disorder. For at least these reasons, Krakovsky fails to disclose or suggest the requirements of Applicant's amended independent claim 28.

Furthermore, Krakovsky fails to disclose or suggest an implantable pulse generator and lead capable of generating and delivering electrical pulses having pulse widths ranging between about 180 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, or between about 10 microseconds and about 5000 microseconds, as required by claim 22. In support of the rejection of claim 22, the Office Action cited FIGS. 12 and 13 of Krakovsky. However, these FIGS. illustrate a pulse width of 0.1 seconds (i.e., 100,000 microseconds), which is outside of each of the ranges recited in claim 22.

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For at least these reasons, the Office Action has failed to establish a *prima facie* case for anticipation of Applicant's claims 1, 7-8, 14 and 20-29 by Krakovsky under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

**Claim Rejection Under 35 U.S.C. § 102/103**

The Office Action rejected claims 1, 9, 14, 24, and 30 under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), as being unpatentable over, "Neural Stimulation as a method of controlling prostatitis systems" (Chalfin), disclosed in 1999 Selected Abstracts from the American Urological Association annual meeting. Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. Chalfin fails to disclose or suggest the inventions defined by Applicant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Chalfin fails to disclose or suggest a method of treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia comprising delivering electrical stimulation pulses to one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Chalfin also fails to disclose or suggest a method for treating at least one of prostatitis, prostatalgia or prostatodynia comprising delivering electrical stimulation pulses to one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof.

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thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 30.

In support of the rejection of Applicant's independent claims 1 and 30, the Office Action stated that implantation of a medical lead adjacent to the sacral nerve necessarily results in the lead being implanted adjacent to other nerves, because nerve structures are close together but not necessarily touching. As discussed above, Applicant has amended independent claims 1 and 30 to clarify that the stimulation pulses are delivered to the specific targets recited in Applicant's claims.

In an alternative rejection, the Office Action stated that the passage of Chaflin which states "the therapy works by applying chronic electrical stimulation to sensory nerves that supply the bladder, rectum and pelvic floor," teaches that Chaflin contemplates stimulation of nerves other than the sacral nerves. In the first paragraph of Chaflin's article, Chaflin describes "unilateral sacral nerve stimulation" therapy and continues to describe the therapy in the second paragraph by stating that "the therapy works by applying chronic electrical stimulation to sensory nerves that supply the bladder, rectum and pelvic floor." In the second paragraph, Chaflin describes unilateral sacral nerve stimulation therapy in further detail and describes the sacral nerves as sensory nerves that supply the bladder, rectum and pelvic floor. Chaflin does not disclose or suggest stimulating any nerves other than sacral nerves, which supply the bladder, rectum and pelvic floor.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1, 9, 14, 24, and 30 by Chalfin under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of this rejection is requested

#### Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 10, 21, 22, and 24 under 35 U.S.C. § 103(a) as being unpatentable over Whitehurst; and rejected claims 4, 5, 7, 8, 10, and 11 under 35 U.S.C. § 103(a) as being unpatentable over Chalfin in view of US 6,055,456 to Gerber (Gerber). Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined

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by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As discussed above, Whitehurst, Krakovsky, and Chafin fail to disclose or suggest each of every feature of Applicant's independent claims 1, 28 and 30, as amended. Gerber does not provide any teaching that would have overcome the basic deficiencies of Whitehurst, Krakovsky, and Chafin with respect to the requirements of the independent claims. For at least these reasons, dependent claims 4, 5, 7, 8, 10, 11, 21, 22 and 24 are also in condition for allowance.

Additionally, the applied references fail to disclose or suggest each and every element of these dependent claims, some of which are discussed below.

The applied references fail to disclose or suggest a lead comprising at least one electrode selected from the group consisting of an electrode formed from a portion of wire, a barb or a hook, a spherically-shaped electrode, and a helically-shaped electrode, as required by claim 11. The Office Action failed to address the requirements of claim 11 as presented in the Amendment dated January 8, 2007. Applicant requests that the requirements of claim 11 be addressed in any subsequent Office Action.

Furthermore, the applied references fail to disclose or suggest an implantable pulse generator and lead capable of generating and delivering electrical pulses having pulse widths ranging between about 180 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, or between about 10 microseconds and about 5000 microseconds, as required by claim 22. In support of the rejection of claim 22, the Office Action reasoned that it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the stimulation system of Whitehurst such that the implantable pulse generator is capable of generating a wide range of stimulation parameters in order to effectively treat each individual's type and degree of sexual dysfunction.

Even if the stimulation system of Whitehurst were modified such that the implantable pulse generator is capable of generating a range of pulse widths, it would not have been obvious to one or ordinary skill in the art at the time of the invention to use the recited pulse width ranges to treat the recited disorders. Applicant's claim 22 recites specific pulse width ranges for treatment of specific disorders. The applied references fail to disclose or suggest using the specific ranges recited in claim 22 to treat at least one of urinary voiding dysfunction, fecal

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voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostataalgia and prostatodynia.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 5, 7, 8, 10, 11, 21, 22 and 24 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

**Rejection for Obviousness-type Double Patenting:**

The Office Action provisionally rejected, under the judicially created doctrine of obviousness-type double patenting: claims 1, 3, 4, 5, 7-11, 14, 20-27, and 39 as being unpatentable over claims 1-27, 36, and 37 of copending Application No. 10/236,578; claims 7-8 as being unpatentable over claims 1, 7, 32 and 38 of copending Application No. 10/723,903; claims 7-8 as being unpatentable over claims 1, 7, 32 and 38 of copending Application No. 10/745,757; claim 27 as being unpatentable over claim 1 of copending Application No. 10/836,355; claim 27 as being unpatentable over claim 1 of copending Application No. 10/836,840; claims 7 and 8 as being unpatentable over claims 1 and 7 of copending Application No. 10/836,924; claims 7 and 8 as being unpatentable over claims 1 and 7 of copending Application No. 10/836,927; claim 27 as being unpatentable over claim 1 of copending Application No. 10/836,970; and claim 27 as being unpatentable over claim 1 copending Application No. 10/837,181.

Applicant respectfully traverses the rejections based on Application Nos. 10/236,578, 10/723,903, 10/745,757, 10/836,355, 10/836,840, 10/836,927 and 10/837,181 (items 2-6, 8, and 10 of the Office Action). These rejections are presently provisional, because the applied applications have not been patented. These rejections can only be formerly applied if the applied applications are patented.

Applicant submits that Application Nos. 10/236,578, 10/723,903, 10/745,757, 10/836,355, 10/836,840, 10/836,927 and 10/837,181 are abandoned. Accordingly, these applications will never be patented. Because the provisional, obviousness-type double patenting rejections based on these applications will never be formerly applied, Applicant respectfully requests that the rejections be withdrawn.

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Applicant notes the provisional status of the rejections based on Application Nos. 10/836,924 and 10/836,970 (items 7 and 9 of the Office Action). Applicant will address this issue if and when the rejection is formally applied.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the claims or applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

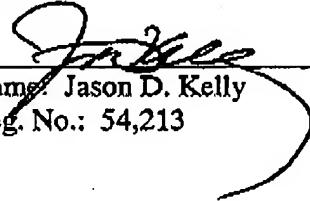
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

8-9-07

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